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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/007,477	11/08/2001	Bret A. Ferree	BAF-10703/29	2845

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GIFFORD, KRASS, GROH, SPRINKLE & CITKOWSKI, P.C  
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EXAMINER

COMSTOCK, DAVID C

ART UNIT	PAPER NUMBER
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3733

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/26/2006	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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# Office Action Summary

Application No.

10/007,477

Applicant(s)

FERREE, BRET A.

Examiner

David Comstock

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3733

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 11 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-3,5,7 and 9-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3,5,7 and 9-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Response to Arguments***

Applicant's arguments, see Appeal Brief, filed 18 May 2006, with respect to the outstanding rejections, have been fully considered and are persuasive. Therefore, the rejections have been withdrawn and the finality of that action is also withdrawn. However, upon further consideration, new grounds of rejection have been set forth below. It is noted that the previous indicated allowability of claims 7 and 9-11 is also withdrawn in view of the following rejections.

### ***Specification***

The reference to the related application in the specification should be amended to reflect that application Serial No. 09/483,805 is now U.S. Patent No. 6,432,107.

Appropriate correction is required.

### ***Claim Objections***

Claim 5 remains objected to because of the following informalities: Claim 5 depends from claim 4, which has been canceled. For purposes of examination, claim 5 will be considered as depending from claim 1. Appropriate correction is required to be responsive to this office action.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 5, 7, 9, 10 and 12-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Kuslich (6,056,749).

Kuslich discloses the claimed invention including a biocompatible fusion device 20, a threaded fastener 100, a separate, removable guide 90, and a corresponding installation method (see, e.g., Figs. 1, 7, 10 and 12-14; col. 1, lines 10-13 and 51-67; and col. 3, lines 23-67). The fusion device 20 is implanted in an intervertebral space wherein the adjacent endplates have been reamed for receipt of the device (see Figs. 10 and 12-14 and col. 3, lines 23-25). The device 20 has a height that is greater than the intervertebral spacing and penetrates into the reamed vertebral bodies (id.). The guide 90 is temporarily mounted on the device 20 (see Figs. 5-7 and 13). The guide is used for drilling a hole 92 for orienting and installing a fastener 100 (Figs. 13 and 14). The fastener 100 extends through the device 20 and the vertebral body (Fig. 14). Regarding apparatus claims 12-17, it is noted that the surfaces 28 and 30, designated as an "upper surface" and a "lower surface," respectively, can be considered lateral surfaces at least because they are in fact positioned laterally when first implanted into a disc space (see col. 3, lines 37-39). Moreover, the device 20 is at least capable of not being rotated into a completely vertical orientation (e.g. when the threads first engage the adjacent vertebral bodies, or any orientation up to the completely vertical orientation). Such a position would be similar to

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that shown in the installation "snapshot" shown in Figure 12. In such a position, the apertures 22 and the surfaces 28 and 30 would comprise a lateral component and could therefore be considered "lateral surfaces," and the fastener is capable of extending through the same. Therefore, the device is considered to at least be capable of meeting the limitations set forth in claims 12-17, pertaining to the way in which the device is intended to be used. It is noted that the reasons that the device is considered to be at least capable of not being completely rotated, as set forth above, are that there are diametrically opposed threaded support surfaces offset from the completely vertical orientation, the device is further stabilized with the fastener 100, and the device is subject to even further stabilization through bone ingrowth (see Fig. 1 and col. 3, lines 55-67).

Claims 1-3, 5, 7, 9-11 and 12-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Graham (5,246,458; cited by Applicant).

Graham discloses an intervertebral implant device 10, 42 with portions 14 having surfaces 108 and protuberances 110 that fuse to spinal bone (see Figs. 3 and 4 and col. 9, lines 14-19). Accordingly, the device can be considered to be an "enhanced-surface area spinal fusion device," as claimed. Graham also discloses a threaded fastener 43, a separate, removable guide 12, and a corresponding installation method (see Figs. 1 and 3-5 and col. 7, line 54 - col. 9, line 19). The implant 10 has a height that is greater than the intervertebral space and it penetrates into and consumes cavities removed from the vertebral bodies (see Figs. 3 and 4). The threaded fastener 43 is installed laterally to extend through the device and the vertebral body. The separate, removable guide 12 is temporarily mounted to the device via fixturing member 52 (see Fig. 5). The guide is used for drilling a hole for orienting and installing the fastener 43.

**Conclusion**


The prior art made of record and not relied upon is considered at least generally pertinent to applicant's disclosure. Day et al. (4,892,545) is applicable to claims 7 and 9 (see, e.g. Figs. 1 and 2). Vaughan (6,899,714) is cited as related art but pertaining to pedicle screws.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Comstock whose telephone number is (571) 272-4710. Please leave a detailed voice message if examiner is unavailable. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached at (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



D. Comstock



EDUARDO C. ROBERT  
SUPERVISORY PATENT EXAMINER